Senate

General Assembly

File No. 398

February Session, 2004

Substitute Senate Bill No. 352

Senate, April 1, 2004

The Committee on Public Health reported through SEN. MURPHY of the 16th Dist., Chairperson of the Committee on the part of the Senate, that the substitute bill ought to pass.

AN ACT CONCERNING THE PREFERRED DRUG LIST AND DRUG PRICING.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Section 17b-274d of the general statutes, as amended by section 19 of public act 03-2, section 63 of public act 03-278 and section 83 of public act 03-3 of the June 30 special session, is repealed and the following is substituted in lieu thereof (*Effective October 1, 2004*):

(a) Pursuant to 42 USC 1396r-8, there is established a Medicaid Pharmaceutical and Therapeutics Committee within the Department of Social Services. Said committee shall convene on or before March 31, 2003.

(b) The Medicaid Pharmaceutical and Therapeutics Committee shall be comprised as specified in 42 USC 1396r-8 and shall consist of fourteen members appointed by the Governor. Five members shall be physicians licensed pursuant to chapter 370, including one general

practitioner, one pediatrician, one geriatrician, one psychiatrist and one specialist in family planning, four members shall be pharmacists licensed pursuant to chapter 400j, two members shall be visiting nurses, one specializing in adult care and one specializing in psychiatric care, one member shall be a clinician designated by the Commissioner of Mental Health and Addiction Services, one member shall be a representative of pharmaceutical manufacturers and one member shall be a consumer representative. The committee may, on an ad hoc basis, seek the participation of other state agencies or other interested parties in its deliberations. The members shall serve for terms of two years from the date of their appointment. Members may be appointed to more than one term. The Commissioner of Social Services, or the commissioner's designee, shall convene the committee following the Governor's designation of appointments. The administrative staff of the Department of Social Services shall serve as staff for said committee and assist with all ministerial duties. The Governor shall ensure that the committee membership includes Medicaid participating physicians and pharmacists, with experience serving all segments of the Medicaid population.

(c) Committee members shall select a chairperson and vice-chairperson from the committee membership on an annual basis.

(d) The committee shall meet at least quarterly, and may meet at other times at the discretion of the chairperson and committee membership. The committee shall comply with all regulations adopted by the department, including notice of any meeting of the committee, pursuant to the requirements of chapter 54.

(e) On or before July 1, 2003, the Department of Social Services, in consultation with the Medicaid and Pharmaceutical Therapeutics Committee, shall adopt a preferred drug list for use in the Medicaid and ConnPACE programs. To the extent feasible, the department shall review all drugs included in the preferred drug list at least every twelve months, and may recommend additions to, and deletions from, the preferred drug list, to ensure that the preferred drug list provides

for medically appropriate drug therapies for Medicaid and ConnPACE patients. **[**For the fiscal year ending June 30, 2004, such drug list shall be limited to three classes of drugs, including proton pump inhibitors and two other classes of drugs determined by the Commissioner of Social Services.**]** The commissioner shall notify the joint standing committees of the General Assembly having cognizance of matters relating to human services, public health and appropriations of the classes of drugs on the list by January 1, 2004.

(f) Except for mental-health-related drugs and antiretroviral drugs, reimbursement for a drug not included in the preferred drug list is subject to prior authorization. No prior authorization shall be required if the patient was using a drug not included in the preferred drug list for the treatment of a chronic illness prior to the adoption of the preferred drug list.

(g) The Department of Social Services shall publish and disseminate the preferred drug list to all Medicaid providers in the state.

(h) The committee shall ensure that the pharmaceutical manufacturers agreeing to provide a supplemental rebate pursuant to 42 USC 1396r-8(c) have an opportunity to present evidence supporting inclusion of a product on the preferred drug list unless a court of competent jurisdiction, in a final decision, determines that the Secretary of Health and Human Services does not have authority to allow such supplemental rebates, provided the inability to utilize supplemental rebates pursuant to this subsection shall not impair the committee's authority to maintain a preferred drug list. Upon timely notice, the department shall ensure that any drug that has been approved, or had any of its particular uses approved, by the United States Food and Drug Administration under a priority review classification, will be reviewed by the Medicaid Pharmaceutical and Therapeutics Committee at the next regularly scheduled meeting. To the extent feasible, upon notice by a pharmaceutical manufacturer, the department shall also schedule a product review for any new product at the next regularly scheduled meeting of the Medicaid

Pharmaceutical and Therapeutics Committee.

(i) Factors considered by the department and the Medicaid Pharmaceutical and Therapeutics Committee in developing the preferred drug list shall include, but not be limited to, clinical efficacy, safety and cost effectiveness of a product.

(j) The Medicaid Pharmaceutical and Therapeutics Committee may also make recommendations to the department regarding the prior authorization of any prescribed drug covered by Medicaid in accordance with the plan developed and implemented pursuant to section 17b-491a.

(k) Medicaid recipients may appeal any department preferred drug list determinations utilizing the Medicaid fair hearing process administered by the Department of Social Services established pursuant to chapter 54.

(l) The provisions of this section shall apply to the state-administered general assistance program.

Sec. 2. (NEW) (*Effective October 1, 2004*) (a) For purposes of this section:

(1) "Health care provider" means any person, corporation, limited liability company, facility or institution operated, owned or licensed in this state to provide health care or professional services, or an officer, employee or agent thereof acting in the course and scope of his or her employment.

(2) "Pharmaceutical marketer" means a person who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in pharmaceutical detailing, promotional activities or other marketing of prescription drugs in this state to any health care provider. "Pharmaceutical marketer" does not include a wholesale drug distributor or the distributor's representative who promotes or otherwise markets the services of the wholesale drug distributor in connection with a prescription drug.

(3) "Detailing" means a meeting between a pharmaceutical marketer and a health care provider in this state for the purpose of discussing a pharmaceutical product being marketed by the pharmaceutical marketer.

(4) "Pharmaceutical manufacturing company" means any entity that is engaged in the production, preparation, propagation, compounding, conversion or processing of prescription drugs, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or any entity engaged in the packaging, repackaging, labeling, relabeling or distribution of prescription drugs, but does not include a wholesale drug distributor or pharmacist licensed under chapter 400j of the general statutes.

(5) "Market price" means the current estimate of the price at which a particular drug is sold by retail pharmacies in this state.

(b) Any pharmaceutical marketer engaged in detailing or other pharmaceutical marketing in this state shall disclose to any health care provider the market price of the drug being detailed or marketed to such health care provider. Each pharmaceutical manufacturing company doing business in this state shall cause all written marketing materials distributed to health care providers in this state to contain information regarding the market price of the drug that is the subject of the marketing materials.

Sec. 3. (*Effective July 1, 2004*) (a) The Commissioner of Public Health shall convene a working group to review drug advertising and marketing practices and their effect on public health and medical costs. The working group shall survey the (1) effects of drug advertising and marketing on prescribing patterns, and (2) costs to the state and private payors arising out of drug advertising and marketing. The working group shall make recommendations for legislation to reduce any negative health care effects resulting from drug advertising and marketing practices, and to limit unwarranted costs to the state and private payors from drug advertising and marketing.

(b) The members of the working group shall be:

(1) A representative from a health care consumer advocacy group appointed by the president pro tempore of the Senate;

(2) A representative from a pharmaceutical company appointed by the speaker of the House of Representatives;

(3) A member appointed by the minority leader of the House of Representatives;

(4) A member appointed by the minority leader of the Senate;

(5) A representative from the Connecticut State Medical Society;

(6) The chairpersons of the joint standing committee of the General Assembly having cognizance of matters relating to public health, or their designees; and

(7) The Commissioner of Public Health, or a designee.

(c) Not later than December 1, 2004, the working group shall submit, in accordance with section 11-4a of the general statutes, a report on its findings and recommendations to the joint standing committees of the General Assembly having cognizance of matters relating to public health, appropriations and the budget of the state, human services and insurance.

This act shall take effect as follows:	
Section 1	*October 1, 2004*
Sec. 2	*October 1, 2004*
Sec. 3	*July 1, 2004*

PH *Joint Favorable Subst.*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 05 $	FY 06 $
Department of Social Services	GF – Savings	Significant	Significant
Legislative Management	GF – Cost	Minimal	Minimal

Municipal Impact: None

Explanation

This bill eliminates the mandate that Department of Social Services' (DSS's) preferred drug list (PDL) be limited to three classes of drugs, thereby expanding the potential numbers of drugs that can be included on the PDL. In FY03, DSS spent over $500 million on pharmaceuticals under various programs. The original FY05 budget included total savings of $15 million from the implementation of the PDL on the three classes of drugs as outlined in current statute. The successful expansion of the PDL beyond these three classes of drugs will lead to increased savings. The amount of these savings will depend upon the implementation schedule of the PDL as well as DSS's ability to negotiate supplemental rebates with the pharmaceutical manufacturers. The revised FY05 budget, sHB 5033 (as favorably reported by the Appropriations Committee), includes an additional $25 million in FY05 PDL savings from this wider implementation.

Establishing a working group to review drug advertising and marketing practices will result in a minimal cost to the Joint Committee on Legislative Management, as legislative members will be entitled to mileage reimbursement.

It is anticipated that the Department of Public Health can participate in the activities of the working group without requiring additional

resources.

OLR Bill Analysis
sSB 352

AN ACT CONCERNING THE PREFERRED DRUG LIST AND DRUG PRICING

SUMMARY:
By law, the Department of Social Services (DSS) must adopt a preferred drug list (PDL) for use in the Medicaid, ConnPACE, and the State Administered General Assistance (SAGA) programs. The department must consult with the Medicaid and Pharmaceutical Therapeutics Committee in developing this list. That committee has 14 members appointed by the governor. Currently, the PDL is limited to three classes of drugs for FY 2003-04: proton pump inhibitors and two other classes of drugs that the DSS commissioner determines. The bill removes this limit, thus expanding the number of drugs that can be on the PDL. It also adds the Public Health Committee to those legislative committees that must be notified of drug classes in the PDL. But notification was to have occurred by January 1, 2004.

Under current law, reimbursement for a drug not included on the PDL, except for mental-health and antiretroviral drugs, is subject to prior authorization. Under the bill, prior authorization is not required if a patient was using a drug not on the PDL for treatment of a chronic illness before the PDL is adopted.

The bill requires pharmaceutical marketers engaged in certain activities in the state to disclose drug market price information to health care providers. Finally, it directs the Department of Public Health (DPH) commissioner to convene a working group to review drug advertising and marketing practices and their effect on public health and medical costs.

EFFECTIVE DATE: October 1, 2004, except that the working group provisions take effect July 1, 2004.

PHARMACEUTICAL MARKETING

The bill requires any pharmaceutical marketer involved in detailing or

other marketing in the state to disclose to the health care provider the market price of the drug being detailed or marketed to him. The "market price" is the current estimate of the price at which a particular drug is sold at retail pharmacies in the state. "Detailing" means a meeting between a pharmaceutical marketer and a provider in the state to discuss a pharmaceutical product. A "pharmaceutical marketer" is someone, who, while employed by or under contract to represent a pharmaceutical manufacturing company, engages in detailing, promotional activities, or other marketing of prescription drugs to any health care provider.

A "health care provider" is any person, corporation, limited liability company, facility or institution operated, owned, or licensed to provide health care or professional services or an officer, employee, or agent of such an entity acting in the course and scope of his employment. A "pharmaceutical manufacturing company" is an entity producing, preparing, propagating, compounding, converting, or processing prescription drugs, either directly or indirectly, by extraction from natural substances, or independently by chemical synthesis, or a combination these techniques. It also includes an entity that packages, repackages, labels, relabels, or distributes prescription drugs, but it does not include a wholesale drug distributor or licensed pharmacist.

WORKING GROUP

The eight-member working group must survey the (1) effects of drug advertising and marketing on prescribing patterns and (2) costs to the state and private payers arising from drug advertising and marketing. It must make legislative recommendations to reduce any negative health care effects resulting from advertising and marketing practices and to limit unwarranted costs to the state and private payers from these practices.

Members include a representative (1) from a health care consumer advocacy group appointed by the Senate president pro tempore, (2) from a pharmaceutical company appointed by the House speaker, (3) from the Connecticut State Medical Society, (4) appointed by the Senate minority leader, and (5) appointed by the House minority leader. The chairmen of the Public Health Committee and the DPH commissioner, or his designee, are also members.

The group must report its findings and recommendations to the Public Health, Human Services, Insurance and Real Estate, and Appropriations committees by December 1, 2004.

BACKGROUND

Prior Authorization

On July 16, 2003, DSS began implementing a prior authorization (PA) program for drugs dispensed under the Medicaid, ConnPACE, SAGA, and General Assistance pharmacy programs.

PA means that before a patient enrolled in any of these programs can get certain drugs, and before pharmacists can get reimbursed for them, DSS must approve the prescription. (DSS has contracted with a company, ACS Healthcare, to run this program.) PA is now required when DSS clients have prescriptions for:

1. with one exception, brand-name drugs when a chemically equivalent generic is available;
2. early refills; and
3. drugs costing more than $ 500 for a 30-day supply.

Individuals who were already taking atypical antipsychotic drugs on July 16, 2003 and continue to need them can receive these drugs without PA. But patients who need these drugs for the first time after July 16, 2003 must get PA.

For brand-name drugs or for early refills of controlled drugs, the prescribing practitioner must request PA. For all others, the pharmacist requests PA.

COMMITTEE ACTION

Public Health Committee

Joint Favorable Substitute
Yea 12 Nay 7